

Notic of Allowability

Application N .

09/665,493

Examin r

Thaian N. Ton

Applicant(s)

MANNING ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on th c ver sh et with th corresp ndence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/4/04.
2. ☒ The allowed claim(s) is/are 17-19.
3. ☒ The drawings filed on 20 September 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachm nt(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Eddie Baba on December 17, 2004.

The application has been amended as follows:

In the specification:

1. Replace page 10, line 12, with the following:

Figure 22A and 22B are the nucleotide sequence of pD10-VEGFuc (SEQ ID NO: 2).
2. Replace page 10, line 22 with the following:

Figure 28A and 28B provide the nucleotide sequence of pD10-sFlt-1 (SEQ ID NO: 3).
3. Replace page 10, line 23 with the following:

Figure 29 is the nucleotide sequence of FGF-20 (SEQ ID NO: 4) and the amino acid sequence of FGF-20 (SEQ ID NO: 5).
4. Replace page 10, line 24 with the following:

Figure 30 is the nucleotide sequence of FGF-21 (SEQ ID NO: 6) and the amino acid sequence of FGF-21 (SEQ ID NO: 7).

5. Replace page 10, line 26 with the following:

Figure 32A and 32B are the nucleotide sequence of pD10K-FGF-2Sc (SEQ ID NO: 8).

Drawings

The drawings are objected to because of the following:

Figure 30 is objected to because it recites "SEQ ID NO: 1 and SEQ ID NO: 2".

Upon review of the figure, the sequences depicted in this figure are found to be SEQ ID NO: 6 and SEQ IDNO: 7. Appropriate correction is required.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement

sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

COLOR DRAWINGS

Applicants' Color Drawing/Photograph (Figure 37), filed on 9/20/00 is not found to fulfill with the requirements for Color Drawings/Photograph set forth in 37 CFR §1.84 and thus, the color drawing/photograph will not be part of this application as issued. Furthermore, in an interview with Eddie Baba, on December 16, 2004, Applicants agreed that such a color drawing/photograph was not desired.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The amendments to the claims and Applicants' arguments overcome the prior rejection, under 112 1st, for enablement, because they recite the specific vector to be used in the claimed method, recombinant AAV. Furthermore, Auricchio *et al.* [Molecular Therapy, 6(4):490-494 (2002)] is post-filing art that supports the enablement of the scope of the invention. In particular, Auricchio teach that AAV

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vectors were used to deliver three anti-angiogenic factors to the eyes of mice that are models of retinopathy of prematurity (see *Abstract* and p. 491) and it was found that this resulted in the inhibition of retinal neovascularization in these mice. See p. 492, 2nd column, *Discussion*.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

twt

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Patent Examiner
Group 1632

JOSEPH WOUTACH
PATENT EXAMINER

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